



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
HEADQUARTERS, US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
810 SCHREIDER STREET
FORT DETRICK, MARYLAND 21702-5000

Office of the Secretary of the General Staff
FOIA #FA-19-0010

5 March 2019

Dr. Remington Nevin
MuckRock News
DEPT MR 63042
411A Highland Avenue
Somerville, MA 02144-2516

Dear Dr. Nevin:

This is in response to your December 11, 2018 Freedom of Information Act request for documents concerning and related to the USAMMDA or other subordinate activity of USAMRMC, and 60 Degrees Pharmaceuticals or any intermediate wholesaler or distributor, for supplies of Tafenoquine (Arakoda) intended for U.S. Military use, from 2013 to the date of processing of this request. The Arakoda (Tafenoquine) Transition Planning Meeting Agenda and meeting minutes with 60P to discuss tafenoquine commercialization documents are enclosed. In accordance with the Freedom of Information Act, information has been withheld (redacted) based on the following exemptions:

Exemption (b)(4) – Permits the withholding of records related to trade secrets and other confidential business information.

Exemption (b)(5) - Permits the withholding of information under the deliberative process privilege, including pre-decisional documents, draft documents, or information that could be withheld under civil discovery, attorney-client, or attorney-work product privileges. Deliberative information consists of recommendations or opinions on legal, policy or other matters that may or may not go directly to the report's approved findings. Pre-decisional information includes intra-agency or inter-agency communications that are antecedent to the adoption of the agency decision. Exemption 5 protects against the premature disclosure of proposed policies and recommendations before they are finally adopted and protects against public confusion that might result from the disclosure of reasons and rationales that may not ultimately be the grounds for an agency's action.

Exemption (b)(6) - Permits the government to withhold information about individuals when the disclosure would constitute a clearly unwarranted invasion into the personal privacy of a third person. When weighing the public interest in knowing how

the government works against the privacy interests of individual persons we may conclude that the requested record contains data of a personal nature and that no significant public interest will be served in the release of that information. Pursuant to Exemption (b)(6), Personally Identifiable Information (PII), to include names, personnel information, social security numbers, email addresses and telephone numbers have been redacted.

Because your request has been partially denied (redacted), you are advised of your right to appeal this determination to the Secretary of the Army. If you decide to appeal at this time, your appeal must be submitted within 90 days of the date of this notification. In your appeal, you must state the basis for your disagreement with the partial denial and the justification for the release of information associated with your request for this command. Your appeal should be addressed to: CDR U.S. Army Medical Command, Attention: Freedom of Information/Privacy Acts Office (MCPA), 2748 Worth Road, JBSA, Fort Sam Houston, Texas 78234-6021, for forwarding, as appropriate, to the Office of the Secretary of the Army. Please enclose a copy of this response along with your Appeal. To ensure proper processing of any appeal, the letter and the envelope should both bear the notation, "Freedom of Information Act Appeal."

Should you have any questions pertaining to the processing of the document I may be reached at (301)-619-7118 or email shalli.l.keller.civ@mail.mil

Respectfully,

A handwritten signature in black ink, appearing to read "Shalli L. Keller", with a long horizontal flourish extending to the right.

Shalli L. Keller
Staff Action Control Officer
Freedom of Information Act Officer
U.S. Army Medical Research and
Material Command

Enclosure

Arakoda™ (Tafenoquine) Transition Planning Meeting Agenda**(b)(5) 0900-1000 (East Coast Time)****Location: USAMMDA Bldg 1430, (b)(5)****(b)(5)****1. Introductions, Purpose of Working Group****(b)(6)****(b)(6)****(b)(6)****2. Review of Issues****(b)(6)****3. Commercialization Plan****(b)(6)****4. Modification of DOD Guidance for Malaria Prophylaxis****(b)(6)****(b)(6)****5. Inclusion of Arakoda™ onto DOD Peacetime Procurement Vehicles and Contingency Contracts****(b)(6)****6. Inclusion of Arakoda™ onto DOD Formularies****(b)(6)****7. Final Discussion**

(b)(5)

MEETING WITH 60P TO DISCUSS TAFENOQUINE COMMERCIALIZATION**PARTICIPANTS:**

(b)(6)

(b)(6)

DISCUSSION:

- Priority Review Designation received for TQ; 6 months for FDA review (completed NLT 8 August 2018)
- (b)(4)
- Timeline:

FDA approval	8 August 2018
Tablet validation	(b)(4)
Packaging validation	(b)(4)
Serialization validation	(b)(4)
Validation lots shipped to distributor	(b)(4)
Commercial launch	(b)(4)

- Trade name: (b)(4)
- 100mg tablets
- JPMPG: When are the future quarterly meetings?
- White paper for consultant community?
- Brief at MHSRS (60P brief)
- Who at DoD-HA can guide us as to how to approach them to get the word out?
- (b)(5)
- Can industry reps approach individual MTFs?
- Three (3) validation lots will have (b)(4)
 - Unit of purchase is (b)(4)
 - One Unit of purchase will provide prophylaxis for one service member for 1 month.
 - Unit of purchase cost = (b)(4) (estimate, based on estimated cost of (b)(4) per tablet)
 - Cost of the 3 validation lots is estimated at (b)(4)
 - (b)(6) could we commit to buying this amount to support placebo-controlled studies? Perhaps post-market night vision studies? Tolerability studies?
- Logistics: (b)(4) is the Third Party Logistician (part of (b)(4))
 - They can also do serialization
 - From (b)(4) → Wholesalers (b)(4) etc)
 - (My NOTE: I think (b)(6) reference to wholesalers is the same as what we term as prime vendor distributor)

- Is there a survey that we can generate to gauge potential use?
 - Summary of Potential Actions for USAMMDA:
 - Can the Army commit to buying a certain amount of TQ to support post-marketing studies?
 - Can industry reps approach individual MTFs?
 - (b)(4)
 - Who at DoD-HA can we contact reference TQ?
 - When are future JPMPG quarterly meetings?
 - Can we persuade DoD-HA to recommend TQ for malaria treatment?
 - Can we get TQ into the appropriate unit assemblages? Need to engage the USAMMA pharmacist.
-

(b)(5) (on/about)

IMPROMPTU MEETING WITH (b)(6)
SUBJECT: POTENTIAL COURSES OF ACTION TO FUND PROCUREMENT OF TAFENOQUINE

According to (b)(6) some courses of action:

- (b)(5)
- (b)(5)
- (b)(5)

Keller, Shalli L CIV USARMY MEDCOM USAMRMC (US)

From: 65311-89460324@requests.muckrock.com
Sent: Tuesday, December 11, 2018 10:40 AM
To: USARMY Ft Detrick MEDCOM USAMRMC List FOIA MPMC
Subject: [Non-DoD Source] Freedom of Information Act Request: Purchase Contracts, Orders, and Records Related to Tafenoquine (Arakoda)

Follow Up Flag: Follow up
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U.S. Army Medical Research and Materiel Command FOIA Office
810 Schreider Street
Frederick, MD 21702-5000

December 11, 2018

Ms. Shalli L Keller
Staff Action Control Officer
U.S. Army Medical Research and Materiel Command
Email: shalli.l.keller.civ@mail.mil
Tel: 301-619-7118

c/o
CDR USAMRMC
810 Schreider Street
Fort Detrick, MD 21702-5000

Re: FOIA Request

Dear Ms. Keller,

This is a request under the Freedom of Information Act. I hereby request the following records:

Copies of all purchase orders, contracts, records, and related correspondence between USAMMDA or other subordinate activity of USAMRMC, and 60 Degrees Pharmaceuticals or any intermediate wholesaler or distributor, for supplies of tafenoquine (Arakoda) intended for U.S. military use, from 2013 to the date of processing of this request.

The requested documents will be made available to the general public, and this request is not being made for commercial purposes.

In the event that there are fees, I would be grateful if you would inform me of the total charges in advance of fulfilling my request. I would prefer the request filled electronically, by e-mail attachment if available or CD-ROM if not.

Thank you in advance for your anticipated cooperation in this matter. I look forward to receiving your response to this request within 20 business days, as the statute requires.

Sincerely,

Dr. Remington Nevin

Filed via MuckRock.com

E-mail (Preferred): 65311-89460324@requests.muckrock.com

Upload documents directly: Caution-https://www.muckrock.com/accounts/agency_login/us-army-medical-research-and-material-command-4063/purchase-contracts-orders-and-records-related-to-tafenoquine-arakoda-65311/?uuid-login=4696f611-18c1-4c06-ae72-e2ae292a4c1b&email=USArmy.Detrick.MEDCOM-USAMRMC.List.FOIA-MRMC%40mail.mil#agency-reply

Is this email coming to the wrong contact? Something else wrong? Use the above link to let us know.

For mailed responses, please address (see note):

MuckRock News

DEPT MR 65311

411A Highland Ave

Somerville, MA 02144-2516

PLEASE NOTE: This request is not filed by a MuckRock staff member, but is being sent through MuckRock by the above in order to better track, share, and manage public records requests. Also note that improperly addressed (i.e., with the requester's name rather than "MuckRock News" and the department number) requests might be returned as undeliverable.

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